

Final Progress Report

“Developing Ethical Practices for Genetics Testing in the Workplace”

U.S. Department of Energy (DE-FG02-04ER63772), 2004-2008

Project conducted February 15, 2004 through February 14, 2008

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Team Development

Our multidisciplinary research team for this project involved collaboration between the Department of Psychiatry and Behavioral Medicine at the Medical College of Wisconsin (MCW) and the Department of Family and Community Medicine at the University of New Mexico Health Sciences Center (UNM HSC).

Our research team in Wisconsin was led by Laura Roberts, M.D., Principal Investigator, and included Scott Helberg, MLS (Project Coordinator), Kate Green Hammond, Ph.D. (Consultant), Krisy Edenharder (Research Coordinator), and Mark Talatzko (Research Assistant).

Our New Mexico-based team was led by Teddy Warner, Ph.D., Co-Principal Investigator and UNM Site Principal Investigator, and included Suzanne Roybal (Project Assistant), Darlyn Mabon (Project Assistant), Kate Green Hammond, PhD (Senior Research Scientist on the UNM team from 2004 until January, 2007), and Paulette Christopher (Research Assistant). In addition, computer technical and web support for the web-based survey conducted on a secure server at the University of New Mexico was provided by Kevin Wiley and Kim Hagen of the Systems and Programming Team of the Health Sciences Center Library and Information Center.

Project Specific Aims

We stated 3 aims in the grant proposal:

- (1) To collect web survey reports of the ethical perspectives, concerns, preferences and decision-making related to genetic testing using surveys from employees at: (a) Los Alamos National Laboratory (LANL); (b) Sandia National Laboratories (SNL); and (c) the University of New Mexico Health Sciences Center (UNMHSC);
- (2) To perform an extensive literature search and the extant survey data to develop evidence-based policy recommendations for ethically sound genetic testing associated with research and occupational health activities in the workplace; and,
- (3) To host a conference at the Medical College of Wisconsin to provide employers, workers, health professionals, researchers, the public, and the media an opportunity to consider ethical issues involved in genetic testing in the context of the workplace.

Two-site Coordination and Timeline

Dr. Roberts traveled to New Mexico and Dr. Warner to Wisconsin annually to collaborate on this project for four years. Dr. Warner also attended presentations about genetic testing,

genetic research, and web-based research methods at various scientific meetings throughout the term of the project. Our original grant proposal timeline had scheduled web survey implementation for the fall of 2005. This schedule was delayed due to Dr. Roberts' move to MCW (which necessitated the establishment of a two-site team) and unanticipated time spent gaining the approval of Los Alamos National Laboratory to conduct the survey with their employees as planned in the grant proposal. At the end of the original 3-years of funding for this project, we requested and were granted a 4th year; during this additional year, we utilized previous unexpended funds to conduct extensive data analysis and interpretation. The original project period was February 15, 2004 through February 14, 2007, but with the one year extension, the project officially ended on February 14, 2008.

AIM 1: Web Survey of Worker Perspectives Regarding Workplace Genetic Testing

Methodological and Procedural Issues As we reported in previous progress reports, we modified the sampling frame described in the grant proposal after an initial consultation with SNL and LANL personnel. Based on these discussions and their decision not to authorize sampling or recruiting access to their email or employment lists for security purposes, we modified the sampling plan to draw self-selected samples stratified by worksites (N=200 per site initially vs. the original N=250 per site) and stratified by 5 broad job categories.

We experienced several procedural issues due to a personnel and institutional change at LANL. As a consequence, we modified our sampling frame to draw 300 survey completers at each of UNM and SNL worksites in this study by major job types (5 stratified basic categories [60 individuals per job category per site] to ensure representation of employees with different job-related exposures and training and background). We did not perform data collection at LANL. This decision was made prospectively with our program officer at the DOE, Dr. Daniel Drell. The proposed protocol modifications were approved by Dr. Drell.

Survey Procedures and Execution. The survey is still located on a secure server maintained by the University of New Mexico and can only be accessed by entering a password which is different than passwords provided to participants in 2006.

The final survey draft was completed in January 2006 after final modifications were made based on pilot testing with 34 individuals of varying job types, educational levels, ages, and gender. Pilot testing showed that most respondents took 30 to 40 minutes to complete the survey. A full copy of the survey is attached to this Final Report.

The final survey includes 188 questions organized in 8 major domains:

- (1) 4 screening questions (worksite, job category, age, length of employment) designed to prevent unqualified individuals from completing the survey;
- (2) 26 general questions about genetics and health;
- (3) 39 questions about confidentiality of health, genetic, and genetic testing information;
- (4) 42 questions about use of genetic information in the workplace;
- (5) 39 questions about volunteer genetic testing;
- (6) 15 questions about general attitudes related to genetic information and genetic testing;
- (7) 17 questions about characteristics of respondents related to genetic testing including exposure to various agents; and

- (8) 6 standard questions about basic characteristics of respondents (gender, educational level, income level, race, ethnicity, marital status, parental status).

Survey recruitment advertisements were sent at UNM and SNL via emails from appropriate staff at each site in mid-September 2006; the ads were repeated in modified form 3 times at SNL and 3 times at UNM. We now have 300 (100%) completed surveys from individuals at UNM and 276 (92%) completed surveys from SNL. Officials at SNL did not want to send a 4th solicitation that may have allowed us to gain response from 100% of the intended 300 desired respondents.

The first page of the survey website (after entry via a password distributed uniquely at each site) is a one-page detailed statement that describes all elements required for informed consent. Individuals consenting to complete the survey must check a response online indicating their consent, which then takes them to the survey itself; checking "no" to the consent statement exits the individual from the survey site.

The first four pages contain carefully worded and organized information about genetic testing and genetic illnesses. The purpose of providing this information prior to content questions for the survey was to ensure a basic understanding of genetic testing and genetic illness-- topics of which many people have relatively little knowledge. We were interested in minimizing the influence of direct knowledge or lack thereof about genetic illness and genetic testing on the responses to survey questions. Instead, we were interested in obtaining responses from UNM and SNL employees based on their thoughts about the ethical, legal and social issues embedded within the questions.

Job information included in the survey questions is general and does not include specific job titles. The next survey page asked for name, address, and phone number to use to issue compensation checks for time and effort from UNM to survey completers of \$40 per person. Only 7 individuals declined to provide names and addresses to gain compensation. Names and addresses were downloaded to a database that is fully independent of the survey question response data and not linkable to it. That EXCEL database was utilized by project staff at UNM to initiate requests to UNM Accounts Payable to issue and mail checks to survey respondents within a few weeks of survey completion.

Responses to all the survey questions were downloaded to an EXCEL database on the UNM secure server. With IRB approval, this de-identified database was transferred to a secure, password protected file at the office of Dr. Warner at UNM. Dr. Warner then transferred copies of this de-identified database to Dr. Roberts and Dr. Green Hammond for collaborative data analysis and manuscript preparation.

The final survey version of 188 questions was refined from the pilot survey that included 563 items from a survey that we conducted with subjects from UNM HSC and SNL in 2001 for the DOE pilot project for this main survey study. Our final survey version was based on what we learned in the pilot survey conducted previously, on further extensive examination of the relevant literature, and on extensive cognitive and basic pilot testing with 34 individual subjects during 2005, as well as consultation with a physician-scientist actively engaged in practice with individuals at risk for various genetic disorders and with a professional genetic counselor on the physician's team. In addition to adding many new items and considering many other new items for the present survey, we worked extensively on the wording, formatting, and scaling of all the items in this new survey to maximize internal and external validity. Hence, the previous pilot

study in 2001 proved to be an essential component to this overall project. After completion of the final survey version in January 2006, we work closely with the programming team at the UNM Health Sciences Center Information Technology Team (ITT) to optimize the clarity of the survey website and the ease with which individuals could interface with it to provide high quality data for this study. We tested and implemented numerous security checks and procedures over several months, and the final survey version was placed onto an active web site on highly secure UNM servers. Then we began extensive online testing of all features and safeguards of our web survey, attempting to “break” the survey in every way conceivable. All problems were sequentially corrected and then retested online. Twelve pilot participants and several members of our research team completed the survey online as a final test.

The implementation of this web survey presented a valuable opportunity to work closely with the Information Technology Team at the Health Sciences Center at UNM. Together, we carefully identified and resolved technological design and implementation issues unique to our project. These included issues related to the distribution of secure private ID’s and passwords at each site, the creation of a design which would allow participants to return to their survey responses if the survey was not completed in one sitting, and the protection of sample integrity—the need both to prevent individuals from non-qualifying sites from completing the survey and to fill cells in the sampling frame appropriately to produce a balanced design. This experience with ITT has benefited our team in many ways; we are now well-positioned to conduct future web surveys and have developed a sophisticated understanding of computer programming and website technology—both its requirements and limitations.

The IRB’s at UNM HSC, MCW, and SNL fully approved the study, the survey, and the survey protocol, including recruitment procedures and web procedures and safeguards. Annual reports have been submitted every 12 months to each of these IRB’s, which have in each case re-approved the project.

Interview of Workers. As with our preliminary study, we randomly selected 5 workers from each of the 5 broad job categories used to stratify the survey respondents from UNM HSC and from SNL who had completed the web survey. Phone interviews were then conducted by Paulette Christopher under the supervision of Dr. Warner. Ms. Christopher is a student in the doctoral clinical psychology program in the Department of Psychology of UNM; she has therefore had substantial training and experience in interviewing. She was further trained in interviewing technique for this project by Dr. Warner. Starting in July and ending in September of 2007, Ms. Christopher completed the 50 interviews by phone for the convenience of participants. Interviews were recorded digitally and recordings were transferred to CD’s without names or other identifiers for transfer to a professional transcription service, which transcribed all interviews for future reference and use in enhancing our understanding of survey data. Interview participants indicated at the end of the web survey their desire to be contacted to be interviewed for additional compensation of \$50. The interview questions and procedures were reviewed and approved by the IRB’s at UNM HSC, SNL, and MCW.

Study Hypotheses. We offered 32 hypotheses (listed below) in the grant proposal for this study. Data analyses have thus far supported several of these hypotheses (**noted below as: “supported”**). Likewise, a number of hypotheses have not been supported by the data in this study (**noted below as: “not supported”**). Analyses are continuing in an effort to provide evidence regarding the remaining hypotheses.

1. Regarding Informed Consent

Hypothesis 1. Employees will be *more likely to consent to voluntary genetic screening or monitoring* if:

- (a) resulting decisions are unlikely to reduce job pay or status
- (b) they are men rather than women **(not supported)**
- (c) job exposure risk is greater **(supported)**
- (d) seriousness of the potential illness is greater
- (e) they work at LANL and SNL rather than UNM Health Sciences Center **(supported)**
- (f) if they were allowed to participate in any subsequent job-relevant decisions **(supported)**

Hypothesis 2. Employees will be *more likely to assent* to required genetic screening or monitoring if:

- (a) resulting decisions are unlikely to reduce job pay or status,
- (b) are men rather than women **(not supported)**
- (c) health hazard exposure risk is great
- (d) seriousness of the potential illness is great
- (e) they work at LANL and SNL rather than UNM Health Sciences Center **(supported)**
- (f) they are allowed to participate in any job relevant decisions that are based on the testing
- (g) screening or monitoring is required of all workers
- (h) screening or monitoring is for a specific occupational hazard rather than a general genetic profile

2. Regarding Handling and Retention of Genetic Samples

Hypothesis 3. Employees will *strongly prefer* that identifiable blood or tissues samples *not* be retained for possible later testing beyond the immediate purpose for which samples were taken. **(partial support)**

3. Regarding Confidentiality and Disclosure

Hypothesis 4. Employees will express *strong concerns* about their personal genetic information being accessed by employers, insurance companies, national or local health databases, and state or federal agencies. **(supported)**

4. Regarding Use of Genetic Information in the Workplace

Hypothesis 5. Employees will find the use of their genetic information by their employers to be *more acceptable* if:

- (a) testing is voluntary
- (b) testing is for serious risks or illnesses **(supported)**
- (c) they can choose whether to disclose the information to their employer or their insurance company
- (d) testing is focused on specific occupational risks rather than general genetic profiles
- (e) the genetic predisposition is stronger **(supported)**
- (f) testing is for applicants rather than current employees **(not supported)**

Hypothesis 6. Employees will find the use of their genetic information by their employers to be *more acceptable* if:

- (a) they are men rather than women **(not supported)**
- (b) they are men or women of reproductive age **(not supported)**
- (c) they have higher levels of education or income or job responsibility **(not supported)**
- (d) they are aware of histories of relevant illnesses within their families **(supported)**
- (e) they are concerned about potential serious or chronic exposure to workplace hazards **(supported)**

Hypothesis 7. Employees at different work sites will have differential concerns about the use of their personal genetic information by their employers that are *consonant with the nature and degree of risks of exposure* at their particular workplace and particular job type. **(partial support)**

Hypothesis 8. In situations where genetic screening or monitoring has revealed employee risk of exposure to specific work hazards in a job, employees will find it *more acceptable* for their employers to require them to change jobs (or not allow them to move to a new riskier job) if:

- (a) the potential illness is more serious
- (b) their genetic predisposition is greater **(supported)**
- (c) they are women rather than men **(not supported)**
- (d) if they work at LANL or SNL rather than UNM Health Sciences Center **(supported)**

AIM 2: Development of Evidence-based Recommendations for Genetic Testing in the Workplace

Although the funding and scope of the original grant proposal was greatly reduced, necessitating the elimination of a national conference (AIM 3) as a formal mechanism for disseminating policy recommendations for genetic testing in the workplace, we remain committed to achieving this aim through the manuscripts we produce from this project.

One example of this is the review article published in *Current Opinion in Psychiatry* in 2005. We conducted a comprehensive literature search in 2004-2005 and submitted an article summarizing our findings: "Ethical issues in the use of genetic information in the workplace." This review includes broad recommendations for conducting genetic testing in the context of work situations in an ethical manner. (See: Geppert, C.M.A. & Roberts, L.W. Ethical issues in the use of genetic information in the workplace: a review of recent developments. *Current Opinion in Psychiatry*, 2005;18:518-524).

A summary of conclusions from that article are:

- New genetic tests and other molecular technology have had immediate and wide relevance to American and European workers. These tests may provide improved workplace safety and protect workers' health, but they may allow discrimination based on acquired genetic information, including the loss of employment, promotion, insurance and health care.
- Clear ethical safeguards are needed if the benefits are to outweigh the adverse consequences of using genetic information in the workplace.
- Recent empirical and conceptual findings stress that genetic testing should only be used with worker fully informed consent and that the workers should control access to their genetic information.
- Genetic testing in work situations is justified only when the information is required to protect the safety of the worker or another person.
- Progress in occupational genetic technology should not be permitted to shift the responsibility for a safe working environment from the employer to the employee.
- Genetic discrimination in all forms is neither supported scientifically nor warranted ethically.
- Occupational physicians and clinicians treating workers will likely have access to potentially stigmatizing genetic information in the future. As a consequence, education and research is urgently needed to expand and implement the

recommendations of major governmental and professional policy statements regarding ethical genetic testing and use of genetic information.

AIM 3: National Ethical Issues in Genetic Testing Conference

With the prospective approval of our Program Officer Daniel Drell, AIM 3 was necessarily dropped from the scope of work for this project (due to significant budget cuts).

Work Products

We have continued to examine data from the original preliminary written survey of 563 items (attached), and we continue to examine data from the 188 question web-based survey (hardcopy attached) for this main project. Dr. Roberts and Dr. Warner and their team have published 3 articles (attached) reporting results, and they expect to publish at least 7 more articles based on data from the web-based survey. The main study attempts to replicate and extend some of the findings from the preliminary study. Thus, we are contributing considerably to the scientific literature about worker concerns about and reactions to genetics testing and related ethical issues. We have also created 2 comprehensive surveys that will serve as the basis for future work and additional data collection in the years ahead from our team and potentially from other researchers in this area.

Published Journal Articles

Geppert, C.M.A. & Roberts, L.W. Ethical issues in the use of genetic information in the workplace: a review of recent developments. Current Opinion in Psychiatry, 2005;18:518-524

Roberts, L.W., Geppert, C., Warner, T.D., Green Hammond, K., Rogers, M., Smrcka, J., Roberts, B. Perspectives on use and protection of genetic information in work settings: results of a preliminary study. Social Science in Medicine, 2005, 60; 1855-1858.

Roberts, L.W., Warner, T.D., Geppert, C., Roberts, M., Green Hammond, K. Employee's perspectives of ethically important aspects of genetic research participation: a pilot study. Comprehensive Psychiatry, 2005, 46; 27-33.

Articles in Preparation for Submission to Journals

All titles of seven manuscripts listed below that are currently in review or preparation are tentative and should not be cited without written permission from the investigators.

Hoop, J., Warner, T.D., Green Hammond, K., Roberts, L.W. Tissue retention of genetic samples in workplace genetic testing. Manuscript under review at Archives of Internal Medicine, 2008.

Roberts, L.W., Warner, T.D., Green Hammond, K., et al. Discrimination based on genetic data obtained from workplace genetic tests. Manuscript in preparation for submission in 2008.

Roberts, L.W., Warner, T.D., Green Hammond, K., et al. Genetic testing and perceptions of health in the workplace. Manuscript in preparation for submission in 2008.

Roberts, L.W., Warner, T.D., Green Hammond, K., et al. Genetic testing and workplace safety. Manuscript in preparation for submission in 2008.

Roberts, L.W., Warner, T.D., Green Hammond, K., et al. Voluntary genetic testing in the workplace. Manuscript in preparation for submission in 2008.

Roberts, L.W., Warner, T.D., Green Hammond, K., et al. Attitudes related to genetic testing among workers. Manuscript in preparation for submission in 2008.

Roberts, L.W., Warner, T.D., Green Hammond, K., et al. Genetic testing and safeguarding confidentiality in the workplace. Manuscript in preparation for submission in 2008.